Considered
9/23/04

Docket No.: 066784-0013 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RESPONSE UNDER 37 CFR 1.116
EXPEDITED PROCEDURE

In re Application of	
Palsczewski et al.	Customer Number: 41552
Serial No.: 09/990,185	Confirmation Number: 1224
Filed: November 21, 2001	Group Art Unit: 1635
	Examiner: ANGELL, Jon E.

For: EXPRESSION OF POLYPEPTIDES IN ROD OUTER SEGMENT MEMBRANES

CERTIFICATE OF MAILING BY EXPRESS MAIL(37 CFR § 1.10) "Express Mail" Mailing Label Number EV 540 267 694 US

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR § 1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on Aug 23, 2004.

Carrie Casey

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

DECLARATION PURSUANT TO 37 C.F.R. § 1.132

I, Juan Ballesteros, declare as follows:

1) I am the Juan Ballesteros named as an inventor of the above-identified application.

2) I am co-founder and Vice President of Research at Novasite Pharmaceuticals. I have held this position since 1999. I received my Ph.D. in molecular biophysics from the Mount Sinai School of Medicine, New York, where I studied under a Fulbright scholarship. Prior to founding Novasite I completed postdoctoral research at both

Mount Sinai and Columbia University. A copy of my Curriculum Vitae is attached as Exhibit A.

3) I understand that the claims under examination stand rejected as allegedly lacking enablement, in part, because the Patent Office asserts that the claims lack a real world utility. Specifically, the Examiner alleges that there are less expensive alternative methods to produce the polypeptides of interest.

4) The claimed gene targeting construct that results in homologous recombination at a mouse rhodopsin gene and the claimed cell and mouse produced from the gene targeting construct are commercially useful for the production of large amounts of the transgenic polypeptide. The transgenic polypeptide can be purified and used in a variety of commercial settings.

5) The commercial usefulness of the claimed invention has been recognized by others. Specifically, Novasite is the recipient of two Small Business Innovation Research (SBIR) awards from the National Institutes of Health (NIH) for the purpose of producing transgenic mice that express a transgene of interest at the rhodopsin gene locus. A grant supporting expression and purification of serotonin receptors was awarded on July 31, 2003, and a copy of the award letter from the NIH is attached as Exhibit B. A contract for the production of endothelial differentiation gene (EDG) receptors was additionally awarded effective September 1, 2003, from the NIH. Novasite also has licensed the above-identified patent application to a well established public biotechnology company for the purpose of generating transgenic mice expressing large amounts of a transgene polypeptide as embodied in the claimed invention. At the request of our partner, the financial details of this multi-year collaborative agreement remain confidential.

6) In conclusion, I believe that the claimed invention has significant real world utility for producing transgenic mice that are useful as a bioreactor for generating large amounts of transgenic polypeptides. The recognition of this utility was shown by the filing of the above-identified application and has been corroborated by others through the award of an SBIR grant and an NIH contract and through the commercial licensing of the patent application.

Serial No.: 09/990,185

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that any such willful false statement may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

Date: 8/23/04 Signature: _____

Name: JUAN BALLESTEROS, PH.D.

Title: VICE PRESIDENT OF RESEARCH AND CSO